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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,814	06/29/2001	Jiangchun Xu	210121.427C26	7420

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/895,814	XU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey Fredman	1634	

-- *Th MAILING DATE of this communication app ars on the cover sh et with th correspondenc address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 3, 4, 8, 11, 15, drawn to nucleic acids, vectors and host cells, classified in class 536, subclass 23.1.
  - II. Claim 2, 7, 11, drawn to proteins, classified in class 530, subclass 350.
  - III. Claim 5, 11, 16, drawn to antibodies, classified in class 530, subclass 387.1.
  - IV. Claim 6, drawn to methods of protein analysis, classified in class 435, subclass 7.1.
  - V. Claim 9, 12, 13, 17, drawn to methods of stimulating T-cells with polypeptides, classified in class 424, subclass 85.1.
  - VI. Claim 9, 12, 13, 17, drawn to methods of stimulating T-cells with nucleic acids, classified in class 514, subclass 44.
  - VII. Claim 9, 12, 13, 17, drawn to methods of stimulating T-cells with antigen presenting cells, classified in class 435, subclass 373.
  - VIII. Claim 10, drawn to isolated T-cells, classified in class 424, subclass 154.1.
  - IX. Claim 14, drawn to methods of detection of cancer, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Group I and VI, II and V, III and VII and VIII are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because each invention is drawn to different products with different chemical structures, different biological functions and which operate in different ways. The nucleic acids of Group I and VI are polymers of nucleotides or use such polymers, that operate by nucleic acid hybridization, while the polypeptides of Group II or V are amino acid polymers, that fold and operate as enzymes, receptors, etc., the antibodies of Group III and VII are recombination products which are designed to specifically bind a particular epitope and the T-cells of Group VIII are entire cells that are selected for particular phenotypes.

3. Inventions in Group I and in Groups IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the nucleic acids are not used in the methods of Groups IV, since the protein analysis methods do not involve the use of a nucleic acid.

4. Inventions in Group I and in Groups VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Group I can be used in detection assays as in Group IX, in treatment methods as in Group VI or in antisense therapy methods or in nucleic acid purification methods or in protein expression methods.

5. Inventions in Group II and in Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein products of Group II can be used in the detection method of Group IV, in the treatment methods of Group V, in purification methods, in enzymatic assay methods, or in antibody synthesis methods.

6. Inventions in Groups II, III, IV, V, VI, VII, VIII and in Group IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because Group IX uses nucleic acids in hybridization assays and Group II-VIII either do not use nucleic acids or use them in treatment methods.

7. Inventions in Group VIII and in Groups V, VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another

and materially different process (MPEP § 806.05(f)). In the instant case, the product of Group VIII can be made by any of the distinct methods of Groups V, VI or VII as well as by purification of T-cells from patients.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct Restriction Subgroups of the claimed invention. By Restriction subgroup, what is meant is that each of the nucleic acid or protein sequences listed in claims 1 and 2 are independent and distinct. Therefore, each independent and distinct nucleic acid or protein sequence constitutes a separate restriction subgroup in the main group. After election of one of the Groups above, Applicant is required to also elect a restriction subgroup of a single nucleic acid. This is not a species election. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Subgroup for prosecution on the merits to which the claims shall be restricted.

**ONLY A SINGLE SEQUENCE WILL BE EXAMINED.**

Applicant is advised that a reply to this requirement must include an identification of the restriction subgroup that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive

unless accompanied by an election. Should applicant traverse on the ground that the Restriction Subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Restriction Subgroups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Monica Steinborn on September 2, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

September 2, 2003